

### REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Claims 1-39 are pending, and claims 4-8 and 16 are under consideration. Claims 4-7 have been amended to more specifically recite certain aspects of the invention, and claim 16 has been cancelled. Support for the amendments may be found throughout the specification and claims as originally filed, and it is urged that the amendments do not constitute new matter. It should also be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

#### Amendment to the Specification

The Reference to Related Applications section has been amended to delete any reference to prior applications, thereby canceling any priority claim to related applications.

#### Objection to the Disclosure

The Action objects to the disclosure for allegedly containing an informality. Specifically, the Action asserts that claim 8 should not recite claims 4 and 5 because claims 4 and 5 already include the complements.

Applicants submit that claims 4 and 5 have been amended to remove reference to complements, thereby obviating this basis of objection. Applicants respectfully request that the objection be withdrawn.

#### Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 4-8 and 16 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. More specifically, the Action alleges that the claims are indefinite in their recitation of the phrases, "variant thereof" and "such that the ability of the variant to react with antigen-specific antisera is not substantially diminished." The Action further asserts that the phrase "antigen-specific antisera" of claim 4 lacks antecedent basis, claims 4-8 and 16 claim



more than was elected for examination, and claim 16 is incomplete because it depends from non-elected claims.

Applicants respectfully traverse this basis of rejection and submit that the claims meet the requirements of Section 112, second paragraph. Applicants submit that the skilled artisan would understand the metes and bounds of the allegedly indefinite phrases. However, without acquiescence to this basis of rejection, Applicants respectfully submit that the claims have been amended to remove the allegedly indefinite phrases and reference to nonelected subject matter. In addition, claim 16 has been cancelled. Applicants further submit that these amendments obviate the basis of rejection and respectfully request that the rejection be reconsidered and withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 4-8 and 16 stand rejected under 35 U.S.C. § 112, first paragraph, on the alleged basis that the specification does not reasonably provide enablement for all polynucleotides that encode polypeptides for which the open reading frame is not disclosed in the polynucleotide encoding that polypeptide, since the instant application allegedly does not disclose all possible open reading frames for the elected polynucleotide of SEQ ID NO:440. The Action acknowledges, however, that the instant specification is enabling for polynucleotides that encode polypeptides for which the open reading frame is disclosed.

Applicants respectfully traverse this basis of rejection and submit that the instant disclosure is enabling for the full scope of the instant claims. Applicants submit that the instant specification teaches how to make and use the claimed polynucleotides, including, *e.g.*, in the diagnosis and treatment of lung cancer. Applicants submit that the claimed invention describes the identification of polypeptide and polynucleotide sequences, including SEQ ID NO:440, also referred to as L200T, that are overexpressed in lung tumor tissue relative to normal lung tissue and, therefore, may be used to detect lung cancer (*see, e.g.*, page 21, line 19 - page 22, line 2 and page 104, lines 2 - 12). Applicants further submit that the skilled artisan would understand that knowledge of all potential open reading frames is irrelevant in the context of using L200T



polynucleotides for the diagnosis of lung cancer, based upon the overexpression of L200T polynucleotides in lung tumor tissue.

In addition, given the correlation between L200T overexpression and lung cancer described in the instant specification, Applicants submit that the skilled artisan would further be enabled to make and use both fragments and variants of L200T for the diagnosis and treatment of lung cancer. Applicants submit that the skilled artisan would readily appreciate that fragments of L200T sequences could be used, for example, in the detection of L200T polynucleotides and for the expression of L200T polypeptides that may be used to generate antibodies and T cells specific for L200T polypeptides. Furthermore, Applicants submit that variants having at least 90% identity to the L200T polynucleotide sequence of SEQ ID NO:440 or being capable of hybridizing to this sequence are also clearly useful in the context of Applicant's invention, *e.g.*, for the detection of L200T polypeptides and the expression of L200T polypeptides. Furthermore, the skilled artisan would readily appreciate that due to the degeneracy of the genetic code, a variety of polynucleotide variants could be generated that would encode the L200T polypeptide and that these variants, as well as others, clearly fall within the scope of Applicants' invention. Applicants further submit that the skilled artisan would be able to make and use the claimed fragments and variants using routine molecular and cell biology techniques, particularly in light of the guidance provided by the instant specification. In addition, Applicants submit that support for polynucleotides comprising at least 415 contiguous nucleotides of the sequence recited in SEQ ID NO:440 is provided, *e.g.*, on page 26, lines 3-12, and support for polynucleotides having at least 90 percent identity to the sequence recited in SEQ ID NO:440 is provided, *e.g.*, on page 25, lines 21-27. Accordingly, Applicants submit that the instant claims are fully enabled and respectfully request that this basis of rejection be reconsidered and withdrawn in light of the above amendments and remarks.

Rejection Under 35 U.S.C. § 102(b)

Claims 4, 7 and 8 stand rejected under 35 U.S.C. § 102(b), for allegedly being anticipated by Hillier *et al.* Specifically, the Action alleges that Hillier *et al.* disclose a DNA that



shares 321 contiguous nucleotides with SEQ ID NO:440 with three mismatches and is, therefore, embraced by these claims.

Applicants respectfully submit that this basis of rejection is obviated by the amendment of claim 4 to recite "an isolated polynucleotide, comprising at least 415 contiguous nucleotides of the sequence recited in SEQ ID NO:440," which is made without acquiescence and solely to expedite prosecution of the instant application. Applicants submit that Hillier *et al.* do not disclose a polynucleotide having at least 415 contiguous nucleotides of the sequence of SEQ ID NO:440. Applicants further submit that support for this amendment is provided in the instant specification, *e.g.*, page 26, lines 3-12. Applicants respectfully request reconsideration and withdrawal of these bases of rejection.

Rejection Under 35 U.S.C. § 102(a)

Claims 4, 7 and 8 stand rejected under 35 U.S.C. § 102(a), for allegedly being anticipated by either one of Cheung *et al.* or Williams *et al.* The Action alleges that Cheung *et al.* discloses a DNA that shares 128 contiguous nucleotides with SEQ ID NO:440 and further alleges that Williams *et al.* discloses a DNA that shares 414 contiguous nucleotides with SEQ ID NO:440.

Applicants respectfully submit that this basis of rejection is obviated by the amendment of claim 4 to recite "an isolated polynucleotide, comprising at least 415 contiguous nucleotides of the sequence recited in SEQ ID NO:440," which is made without acquiescence and solely to expedite prosecution of the instant application. Applicants submit that neither Cheung *et al.* nor Williams *et al.* discloses a polynucleotide having at least 415 contiguous nucleotides of the sequence of SEQ ID NO:440. Applicants further submit that support for this amendment is provided in the instant specification, *e.g.*, page 26, lines 3-12. Applicants respectfully request reconsideration and withdrawal of these bases of rejection.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.



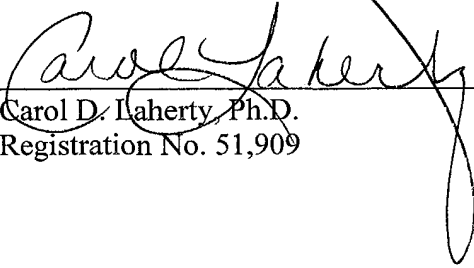
Application No. 09/667,170  
Reply to Office Action dated May 27, 2003

Applicants respectfully submit that all claims remaining in the application are now believed allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. Applicants' attorney wishes to express her willingness to engage in a telephone interview to further the status of this application if any further concerns need to be addressed.

Respectfully submitted,

Steven G. Reed *et al.*

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